FDA 510(k) Premarket Notification

K212659 More-Cell-System

CLEARED

Nov 10, 2021
79 days to decision

K212659 · Product code: **PMU** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k212659/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Containment System, Laparoscopic Power Morcellation, With Instrument Port (PMU)
Date received	Aug 23, 2021
Decision date	Nov 10, 2021
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Agency For Medical Innovations GmbH**
Location	Feldkirch, AT
Contact	Martin Hohlrieder
510(k) history	4 submissions · 4 cleared · 2015-2021

REGULATORY CONSULTANT

Consulting firm	**Acknowledge Regulatory Strategies, LLC**
Contact	Allison Komiyama

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov